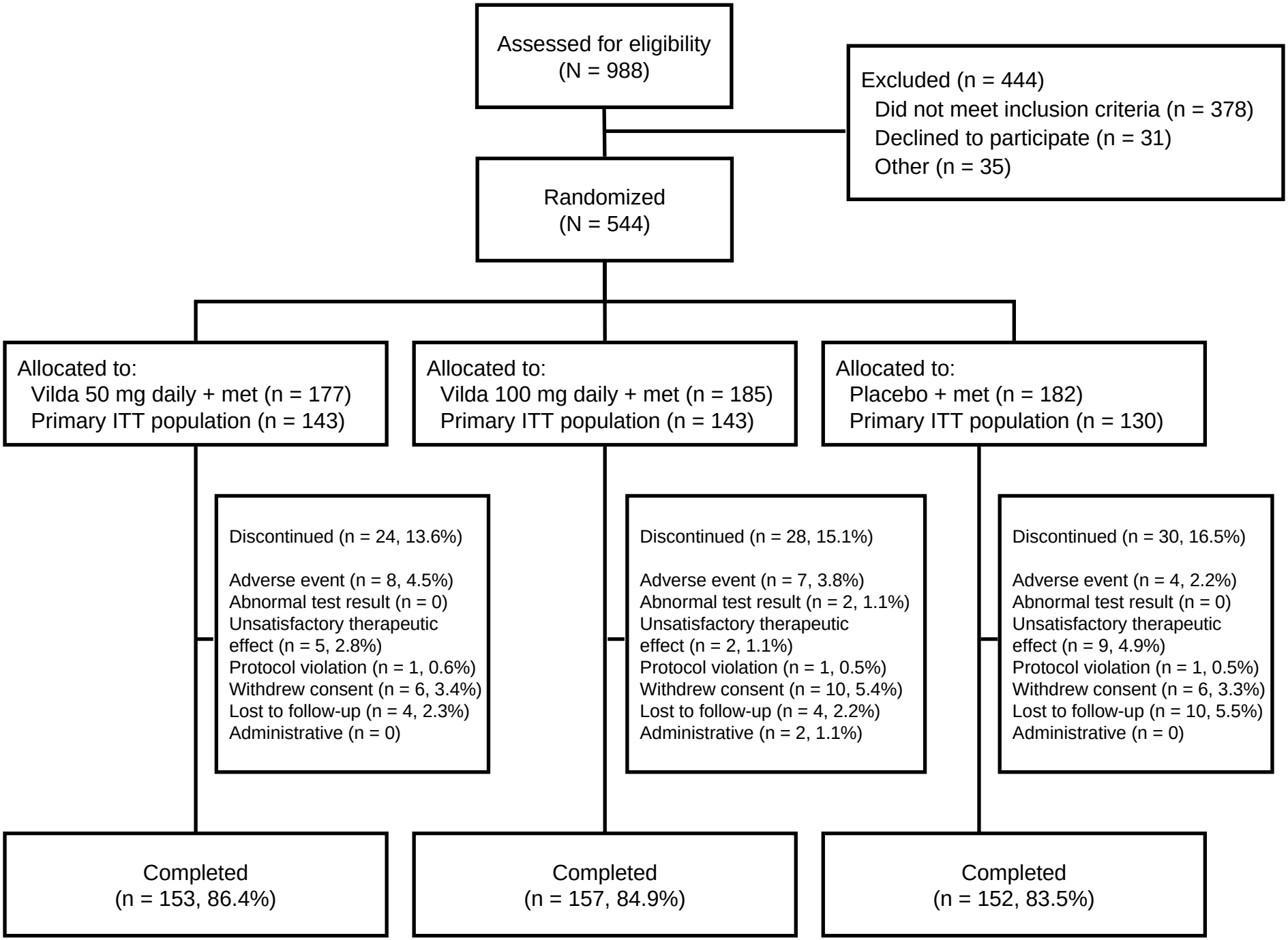
Assessed for eligibility
(N = 988)
Excluded (n = 444)
Did not meet inclusion criteria (n = 378)
Declined to participate (n = 31)
Other (n = 35)
Randomized
(N = 544)
Allocated to:
Vilda 50 mg daily + met (n = 177)
Primary ITT population (n = 143)
Allocated to:
Vilda 100 mg daily + met (n = 185)
Primary ITT population (n = 143)
Allocated to:
Placebo + met (n = 182)
Primary ITT population (n = 130)
Discontinued (n = 24, 13.6%)
Adverse event (n = 8, 4.5%)
Abnormal test result (n = 0)
Unsatisfactory therapeutic effect (n = 5, 2.8%)
Protocol violation (n = 1, 0.6%)
Withdrew consent (n = 6, 3.4%)
Lost to follow-up (n = 4, 2.3%)
Administrative (n = 0)
Discontinued (n = 28, 15.1%)
Adverse event (n = 7, 3.8%)
Abnormal test result (n = 2, 1.1%)
Unsatisfactory therapeutic effect (n = 2, 1.1%)
Protocol violation (n = 1, 0.5%)
Withdrew consent (n = 10, 5.4%)
Lost to follow-up (n = 4, 2.2%)
Administrative (n = 2, 1.1%)
Discontinued (n = 30, 16.5%)
Adverse event (n = 4, 2.2%)
Abnormal test result (n = 0)
Unsatisfactory therapeutic effect (n = 9, 4.9%)
Protocol violation (n = 1, 0.5%)
Withdrew consent (n = 6, 3.3%)
Lost to follow-up (n = 10, 5.5%)
Administrative (n = 0)
Completed
(n = 153, 86.4%)
Completed
(n = 157, 84.9%)
Completed
(n = 152, 83.5%)